Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference **A41266A**	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. **PCT/JP2004/005167**	International filing date *(day/month/year)* **09.04.2004**	Priority date *(day/month/year)* **11.04.2003**
International Patent Classification (IPC) or national classification and IPC		

Applicant

RIKEN

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of **6** sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☒	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/005167

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* _____ received by this Authority on _____

nos.* _____ received by this Authority on _____

☐ the drawings:

sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

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Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	2-7, 10-17, 22, 23, 26-30	YES
	Claims	1, 8, 9, 18-21, 24, 25, 31	NO
Inventive step (IS)	Claims		YES
	Claims	1-31	NO
Industrial applicability (IA)	Claims	1-31	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: JP 06-343478 A (Hitachi, Ltd.), 20 December 1994 (Family: none)

Document 2: US 6063629 A (Wolfgang Lummel), 16 May 2000 & EP 0992577 A1

Document 3: JP 2003-088383 A (President of Tokyo Institute of Technology), 25 March 2003 (Family: none)

Document 4: WO 1999/046361 A1 (Masao Karube), 16 September 1999 & EP 1063287 A1

Claims 1, 8, 9, 18 to 21, 24, 25 and 31

Document 1 sets forth a microinjection method and device therefor, wherein a physiologically active substance such as nucleic acid is immobilized by electrodeposition on the tip of a needle, the needle is inserted into the target area of a cell and the substance is injected into the target area. Document 1 also indicates that a needle with a diameter not exceeding 0.5 microns fabricated from tungsten wire is used as said needle. Therefore the inventions set forth in claims 1, 8, 9, 18 to 21, 24, 25 and 31 lack novelty and do not involve an inventive step in the light of document 1.

Claims 3, 4, 10 to 17, 22, 23 and 26 to 30

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

In the microinjection method and device therefor set forth in document 1, it would be common practice and easy for a person skilled in the art to specify the shape of the needle; to optimize electrical conditions for immobilizing the substance to be injected according to the substance to be injected; to maintain a cultivation environment for cells; to have a piezoelectric element serve as the drive means; and to clean used needles. Therefore the inventions set forth in claims 3, 4, 10 to 17, 22, 23 and 26 to 30 do not involve an inventive step in the light of document 1.

Claim 2

Document 2 indicates that the diameter of the tip of a nanopipette is set to fall within the range of 0.025 to 0.3μm in order to reduce damage to cells in microinjection. It would be easy for a person skilled in the art to set the needle diameter as described in document 2 in the invention set forth in document 1 in order to reduce damage to cells. Therefore the invention set forth in claim 2 does not involve an inventive step in the light of documents 1 and 2.

Claims 5 to 7

Document 3 sets forth needles made from metal oxide whiskers, carbon nanotube and the like as the needles used to puncture living cells. Document 4 sets forth an invention made from silicon as a needle-shaped support used in microinjection. It would be easy for a person skilled in the art to conceive of employing the material set forth in document 3 or document 4 in the invention

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

set forth in document 1. Therefore the invention set forth in claims 5 to 7 does not involve an inventive step in the light of documents 1, 3 and 4.

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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
JP 2003-325161 A [PX]	18.11.2003	28.02.2003	06.03.2002

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)